K092550

Summary of Safety and Effectiveness

July 20, 2009

1. Submitter's Information

Common/Usual Name: Image Viewing System

Proprietary Name: TiGRT IVS, TiGRT

DEC 15 2009

Applicant Name and Address:

LinaTech, LLC
1294 Kifer Road, #705
Sunnyvale, CA 94086
Telephone: 408-733-2051
Fax: 408-733-2045

2. Predicate Devices

ExacTrac (K072046)

3. Classification

This device is classified as a Class II device according to 21 CFR 892.5050.

4. Performance Standards

No applicable standards have been established by FDA under section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description

TiGRT IVS is intended to be used in conjunction with Linac and Digital Panel for analyzing the current patient position and calculating the patient positioning shift correction factor, as well as the treatment portal verification and record.

The intended use is the same as the predicate device.

6. Biocompatibility

No new issues of biocompatibility are raised with regard to this device.

7. Summary of Substantial Equivalence

This device is similar in design and construction, and has the same intended use and performance characteristics to the predicate device. It utilizes materials that are already in use in other medical devices. No new issues of safety or effectiveness are introduced by using this device.

Table 1: Comparison of TiGRT IVS Modified Device with Predicate Device

Characteristic	Current Modified Device TiGRT IVS	Predicate Device ExacTrac (K072046)
Operating System	Windows XP / Vista / 7	Windows XP Professional
Networking	TCP/IP	TCP/IP
Intended Use	TiGRT IVS is intended to be used in conjunction with Linac and Digital Panel for analyzing the current patient position and calculating the patient positioning shift correction factor, as well as the treatment portal verification and record.	The ExacTrac 3rd party system is intended to be used in conjunction with the MHI-TM2000 radiation therapy linear accelerator system manufactured by Mitsubishi Heavy Industries, Ltd. ExacTrac 3rd Party uses the images received from the MHI-TM2000 linear accelerator for analyzing the current patient position and calculating – when applicable – a necessary correction shift. The correction shift is then exported to the MHI-TM2000 linear accelerator. The ExacTrac 3rd Party system uses stereoscopic x-ray or cone beam CT registration and optical tracking of infrared reflective markers in order to localize and correct the patient position before and during treatment.
Application(Use)	Patient tracking and positioning, Portal verification and record,	Patient tracking and positioning, Portal verification and record.
DICOM	DICOM 3/RT	DICOM 3/RT

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Jonathan Yao, Ph.D.
President and CEO
LinaTech LLC
1294 Kifer Road, Suite 705
SUNNYVALE CA 94086

DEC 15 2009

Re: K092550
Trade/Device Name: TiGRT IVS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 30, 2009
Received: November 5, 2009

Dear Dr. Yao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K092550

Device Name: TiGRT IVS

Indications for Use:

TiGRT IVS is intended to be used in conjunction with Linac and Digital Panel for analyzing the current patient position and calculating the patient positioning shift correction factor, as well as the treatment portal verification and record.

(PLEASE DO NOT WRITE BELLOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓ OR Over-The-Counter Use _____(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092550